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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,644	01/15/2004	Peter Wernet	07588/026003	5815
21559	7590	09/06/2005	EXAMINER	
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			NGUYEN, QUANG	
			ART UNIT	PAPER NUMBER
			1633	

DATE MAILED: 09/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/758,644

Applicant(s)

WERNET, PETER

Examiner

Quang Nguyen, Ph.D.

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration:
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Claims 1-21 are pending in the present application, and they are subjected to the following restrictions.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 3 and 14, drawn to **a method of treating a vascular disease in a human patient**, said method comprising administering to said patient unrestricted somatic stem cells (USSCs), classified in class 424, subclass 93.1.
- II. Claims 4 and 16, drawn to **a method of treating a disease of the cardiac muscle in a human patient**, said method comprising administering to said patient unrestricted somatic stem cells (USSCs), classified in class 424, subclass 93.1.
- III. Claims 4 and 16, drawn to **a method of treating a disease of the smooth muscle in a human patient**, said method comprising administering to said patient unrestricted somatic stem cells (USSCs), classified in class 424, subclass 93.1.
- IV. Claims 5 and 17, drawn to **a method of treating a hepatic disease in a human patient**, said method comprising administering to said patient unrestricted somatic stem cells (USSCs), classified in class 424, subclass 93.1.

- V. Claims 6 and 18, drawn to **a method of treating a type I diabetes in a human patient**, said method comprising administering to said patient unrestricted somatic stem cells (USSCs), classified in class 424, subclass 93.1.
- VI. Claims 7-8 and 19-20, drawn to **a method of treating a neural disease in a human patient**, said method comprising administering to said patient unrestricted somatic stem cells (USSCs), classified in class 424, subclass 93.1.
- VII. Claims 9 and 21, drawn to **a method of treating a hematological disease in a human patient**, said method comprising administering to said patient unrestricted somatic stem cells (USSCs), classified in class 424, subclass 93.1.
- VIII. Claim 14, drawn to **a method of treating a vascular disease in a human patient**, said method comprising administering to said patient **differentiated progeny of unrestricted somatic stem cells (USSCs)**, classified in class 424, subclass 93.1.
- IX. Claim 16, drawn to **a method of treating a disease of the cardiac muscle in a human patient**, said method comprising administering to said patient **differentiated progeny of unrestricted somatic stem cells (USSCs)**, classified in class 424, subclass 93.1.
- X. Claim 16, drawn to **a method of treating a disease of the smooth muscle in a human patient**, said method comprising administering to

said patient **differentiated progeny of unrestricted somatic stem cells (USSCs)**, classified in class 424, subclass 93.1.

- XI. Claim 17, drawn to a **method of treating a hepatic disease in a human patient**, said method comprising administering to said patient **differentiated progeny of unrestricted somatic stem cells (USSCs)**, classified in class 424, subclass 93.1.
- XII. Claim 18, drawn to a **method of treating a type I diabetes in a human patient**, said method comprising administering to said patient **differentiated progeny of unrestricted somatic stem cells (USSCs)**, classified in class 424, subclass 93.1.
- XIII. Claims 19-20, drawn to a **method of treating a neural disease in a human patient**, said method comprising administering to said patient **differentiated progeny of unrestricted somatic stem cells (USSCs)**, classified in class 424, subclass 93.1.
- XIV. Claim 21, drawn to a **method of treating a hematological disease in a human patient**, said method comprising administering to said patient **differentiated progeny of unrestricted somatic stem cells (USSCs)**, classified in class 424, subclass 93.1.

Claims 1-2 and 10-11 link a plurality of distinct inventions of Groups I-VII using unrestricted somatic stem cells (USSCs). This is because a method for treating a disease that encompasses distinct diseases such as a vascular disease, a disease of the cardiac muscle, a disease of the smooth muscle, a hepatic disease, a type I

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diabetes disease, a neural disease and a hematopoietic disease that have different causes, symptoms, tissue source and disease progression one from the others. Therefore, the methods for treating these distinct diseases would require different technical considerations for achieving the therapeutic results desired by Applicants.

Similarly, claims 10-13 link a plurality of distinct inventions of Groups VIII-XIV using differentiated progeny of unrestricted somatic stem cells (USSCs). This is because a method for treating a disease that encompasses distinct diseases for the same reasons set forth in the preceding paragraph.

Upon the allowance of the linking claims, the restriction requirement as to the linked invention shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims or the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-132(CCPA 1971). See also MPEP 804.01.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-XIV are drawn to distinct methods having different starting materials (e.g., a human patient with distinct diseases using either unrestricted somatic stem cells

or differentiated progeny of unrestricted somatic stem cells) that require different technical considerations for achieving the different desired therapeutic results appropriate for the treated diseases. It should be noted that USSCs and its differentiated progeny are distinct cell populations that have different biological or biochemical properties one from the others.

Because these inventions are distinct for the reasons given above, and separate search requirements due to the distinctness of each Invention as discussed above in both patented and non-patented literature. Please note that the search for the treatment method of a given distinct disease may not overlap with the search for the treatment method of other distinct diseases. Likewise, the search for the treatment method using a differentiated progeny of USSCs appropriate for a given distinct disease may not overlap with the search for the treatment method of the same disease using USSCs, let alone other distinct diseases. Therefore, it would be unduly burdensome for the examiner to **search and/or consider the patentability** (examination) of all the inventions in a single application. Accordingly, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17 (h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, David Guzo, Ph.D., may be reached at (571) 272-0767, or SPE, Dave Nguyen, at (571) 272-0731.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.


QUANG NGUYEN, PH.D
PATENT EXAMINER